



Horizon Pharma, Inc. Announces FDA Acceptance of DUEXA[®] New Drug Application for Filing

NORTHBROOK, Ill. — May 26, 2010 — Horizon Pharma, Inc., a late-stage biopharmaceutical company focused on the development and commercialization of innovative medicines for pain-related diseases and inflammation, today announced that its New Drug Application (NDA) for DUEXA[®], a proprietary tablet formulation containing a fixed-dose combination of ibuprofen and high-dose famotidine, was accepted by the U.S. Food and Drug Administration (FDA) for review. Horizon is seeking FDA approval of DUEXA for the reduction of the risk of development of upper gastrointestinal ulcers in patients with arthritis and pain. The PDUFA date for completion of the FDA's review for DUEXA is expected in the first quarter of 2011.

“As the pain and arthritis market continues to grow, safe and effective treatments are desperately needed for physicians and patients concerned about the gastrointestinal impact of NSAIDs,” said Timothy P. Walbert, chairman, president and chief executive officer of Horizon Pharma. “We look forward to working closely with the FDA to bring DUEXA to market as quickly as possible. The filing of the DUEXA NDA brings us one step closer to providing the millions suffering from mild-to-moderate pain and arthritis with a new treatment option.”

The DUEXA NDA submission was based on two Phase 3 clinical studies (REDUCE-1 and REDUCE-2), which demonstrated that patients with mild-to-moderate pain treated with DUEXA developed approximately fifty percent less upper gastrointestinal (GI) ulcers) compared to patients treated with ibuprofen alone. The trials were conducted in the U.S. via a Special Protocol Assessment (SPA) with the FDA and enrolled more than 1,500 patients. Based on these data, the Company also plans to submit a marketing authorization application (MAA) for DUEXA in the European Union through the Decentralized Procedure in the second half of 2010.

About DUEXA

DUEXA is a novel, proprietary fixed-dose tablet combining the one of the world's most prescribed NSAIDs, ibuprofen, with a high dose of the most potent H₂ antagonist, famotidine, in a single pill. Ibuprofen has proven anti-inflammatory and analgesic properties, whereas famotidine reduces the stomach acid secretion that can cause gastric and duodenal ulceration. By combining ibuprofen and famotidine into a single product, it is believed that ibuprofen's gastrointestinal safety profile will be improved without altering its ability to reduce pain and inflammation.

About the Arthritis and Pain Market

According to the Arthritis Foundation, arthritis affects 46 million people in the U.S. and costs the U.S. economy \$128 billion annually. According to a study by the Centers for Disease Control and Prevention (CDC) for the National Arthritis Data Workgroup, due to the increasing aging population, arthritis is projected to increase by 40 percent in the next two decades. The CDC estimates that 67 million people in the U.S. will be affected by arthritis by 2030. Additionally, chronic pain affects an estimated 86 million American adults. NSAIDs are among the most widely used drugs in the world for the treatment of arthritis and pain and are a major cause of GI complications, including ulcers. NSAIDs block enzymes and reduce prostaglandins throughout the body and as a consequence, ongoing inflammation, pain, and fever are reduced. Because the prostaglandins that protect the stomach are reduced, NSAIDs often cause ulcers in the stomach. NSAID-induced GI toxicity causes an estimated 16,500 deaths and more than 107,000 hospitalizations annually in the U.S. alone.

Recently published data also indicates that physicians only co-prescribe GI protective agents 27 percent of the time. In addition, historical data has shown that, by the third prescription, over 60 percent of patients stop taking their prescribed GI co-therapy.



About Horizon Pharma

Horizon Pharma, Inc. is a late-stage biopharmaceutical company focused on the development and commercialization of innovative medicines for pain-related diseases and chronic inflammation. Horizon's product portfolio includes innovative therapies in early- and late-stage development that are designed to improve the efficacy, safety and quality of life for patients with chronic pain and inflammation. Horizon's most advanced product is LODOTRA, a circadian cytokine modulator (CCM) for the treatment of the signs and symptoms of rheumatoid arthritis (RA), which has received a recommendation for granting of a national marketing authorization in certain Member States of the European Union. L ODOTRA is already launched in Germany. The company's lead development stage product is DUEXA, a novel, proprietary fixed-dose tablet combining one of the most prescribed NSAIDs in the world, ibuprofen, with a high dose of the most potent H₂ antagonist, famotidine, in a single pill. In two Phase 3 clinical studies (REDUCE-1 and REDUCE-2), DUEXA was shown to significantly reduce the incidence of NSAID-induced upper gastrointestinal (GI) ulcers in patients with mild-to-moderate pain and arthritis. The Company is financed by leading life-science investors Atlas Venture, Deutsche Bank AG, London, Essex Woodlands Healthcare Ventures, FirstMark Capital, Global Life Science Ventures, NGN Capital, Scale Ventures, Sutter Hill Ventures and TVM Capital.

For more information about the company and its products, please visit www.horizonpharma.com.

Forward Looking Statements

This press release includes forward-looking statements that are subject to risks, uncertainties and other factors. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including, but not limited to, any statements regarding the future of any product or product candidate, including the timing of the submission of regulatory filings for approval of such products or product candidates and the timing of any regulatory approval; and any statements of the plans, strategies and objectives of management for future operations of the company. Such statements are only predictions, and actual events or results may differ materially from those projected in such forward-looking statements. Factors that could cause or contribute to the differences include, but are not limited to, the inherent risks of product development and approval, clinical outcomes, regulatory risks, risks related to proprietary rights, market acceptance and competition and risks associated with the company's ability to obtain additional capital to support its planned operations.

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